REMARKS

Claims 1-8, 10-17 and 21-32 are pending. In the Office Action mailed March 21, 2006, the Examiner acknowledged Group I Claims 1-17 and 21-32, as they relate to SEQ ID NO:05, and that it was proper to keep SEQ ID NO:05 and NO:04 together, and further stated that "claims directed to SEQ ID NO:01 will also be examined." In addition, the Examiner withdrew non-elected sequences, and made numerous objections and rejections to the pending claims. Each objection and rejection is addressed below.

Claims are currently amended, notwithstanding Applicants' belief that the cancelled and unamended claims would have been allowable, without acquiescing to any of the Examiner's arguments, and without waiving the right to prosecute the unamended (or similar) claims in another application, but rather for the purpose of furthering Applicant's business goals and expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG).[1]

I. Affirmation of Election of Sequences

The Examiner states that Claims 1-8, 10-17 and 21-32 are pending as "linking claims that link the individual sequences recited in claim 10" and subject to a "nonallowance of the linking claims. Upon the allowance of the linking claims, the restriction requirement as to the linked inventions shall be withdrawn and any claimed depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant applications." The Applicants now amend the claims to read only on the elected sequence(s) in order to further their business interests and the prosecution of the present application, yet without acquiescing to the Examiner's arguments, and while preserving the right to prosecute the canceled (or similar) claims and/or sequences in the future.

II. Specification: Redaction of Embedded Hyperlinks

The Examiner objects to embedded hyperlinks, particularly on pages 43 in line 1 paragraph [0156], 46 in line 19 paragraph [0169], page 48 in line 7 paragraph [0174],

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[1] 65 Fed. Reg. 54603 (September 8, 2000).

page 98 in lines 11 and 30 paragraphs [0326] [0328], page 99 in lines 20 and 25-27 paragraphs [0330] [0331], page 102 line 25 paragraph [0339], and page 104 in line 12 paragraph [0342]. (Office Action mailed March 21, 2006, page 3). The Applicants now amend the Specification to remove all embedded hyperlinks.

III. Abstract

The Examiner objects to the abstract "because it is not descriptive enough of the elected invention. Applicant is advised to amend the abstract to include the organism from which the gene has been taken." (Office Action mailed March 21, 2006, page 4). The Applicants now amend the abstract to include the organism, please see, Amendments to the Specification, page 7. Further, the Examiner states "The abstract should be between 50-150 words in length . . ." (Office Action mailed March 21, 2006, page 4). The Applicants point out that the amended Abstract contains 19 additional words, thus the Abstract is now 59 words in length.

IV. Title

The Examiner objects to the Title as "not descriptive." A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested: - - LUT1 gene from Arabidopsis and its use in engineering carotenoid metabolism in plants - - ." (Office Action mailed March 21, 2006, page 4). The Applicants respectfully disagree. The suggested title is not clearly indicative of the invention. Therefore, the Applicants do not amend the current title.

V. Indefiniteness Rejections

Claims 5-8, 13 and 16-17 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter containing subject matter which applicant regards as the invention. (Office Action mailed March 21, 2006, page 5).

In regard to Claims 5-8, the Examiner takes issue with the word "corresponding" in relation to an identified sequence. The Examiner states "The use of the word

"corresponding" renders these claims indefinite." (Office Action mailed March 21, 2006, page 5). As amended, Claims 5-8 do not use the word "corresponding."

In regard to Claim 13, the Examiner takes issue with "plant vector comprises a T-DNA vector." The amendment to claim 13 obviates this rejection.

In regard to Claims 16-17, the Examiner points out a limitation of "said promoter" in line 1. As amended, Claims 16-17 do not include "promoter" in the preamble.

VI. Written Description Rejections

Claims 1, 15, 21, and 25-31 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. (Office Action mailed March 21, 2006, pages 5-7). In particular, the Examiner states, "The only proven functional activity is the ability of SEQ ID NO:4 or 5 to complement the lut1 mutation in Arabidopsis. However, the specification does not describe any structural features that correspond to the functional activity of being able to complement the *lut1* mutation." (Office Action mailed March 21, 2006, page 5). The Applicants respectfully disagree. The Application teaches the sequence, which is itself structural information plainly understood by a person of ordinary skill in the art. In particular, the specification that a LUT1 sequence complemented a *lut1* mutation. (*See*, Application as published, Examples 3 and 5). Further, the Applicants provide a description of structural features of LUT1. (*See*, Application as published, EXAMPLE 4). Moreover, structural features identified and described for LUT1 allowed the Applicants to further identify known LUT1 Homologs in Other Species, (*See*, Application as published, EXAMPLE 6).

Further, the Examiner's attention is respectfully directed to the Federal Circuit's recent holding in Falkner v. Inglis, 448 F.3d 1357; 79 U.S.P.Q.2D (BNA) 1001 (Fed. Cir. 2006). In that case, the Federal Circuit specifically held that "Eli Lilly does not set forth a per se rule that whenever a claim limitation is directed to a macromolecular sequence, the specification must always recite the gene or sequence, regardless of whether it is known in the prior art." Id. at 1367. The Federal Circuit went on to explain that:

> Thus, "[w]hen the prior art includes the nucleotide information, precedent does not set a per se rule that the information must be determined afresh." Id. at 1358. Rather, we explained that:

> The descriptive text needed to meet these requirements varies with the nature and scope of the invention at issue, and with the scientific and technologic knowledge already in existence. The law must be applied to each invention that enters the patent process, for each patented advance is novel in relation to the state of the science. Since the law is applied to each invention in view of the state of relevant knowledge, its application will vary with differences in the state of knowledge in the field and differences in the predictability of the science.
> Id. at 1357.

Indeed, a requirement that patentees recite known DNA structures, if one existed, would serve no goal of the written description requirement. It would neither enforce the quid pro quo between the patentee and the public by forcing the disclosure of new information, nor would it be necessary to demonstrate to a person of ordinary skill in the art that the patentee was in possession of the claimed invention. As we stated in Capon, "[t]he 'written description' requirement states that the patentee must describe the invention; it does not state that every invention must be described in the same way. As each field evolves, the balance also evolves between what is known and what is added by each inventive contribution." Id. at 1358. Indeed, the forced recitation of known sequences in patent disclosures would only add unnecessary bulk to the specification.

Id. at 1367-68. As held by the Federal Circuit in Falkner, "Since the law is applied to each invention in view of the state of relevant knowledge, its application will vary with differences in the state of knowledge in the field and differences in the predictability of the science." Falkner, 448 F.3d at 1367-68. It is beyond doubt that as of the filing date of the instant invention, a person of ordinary skill in the art could make and identify nucleic acid sequences encoding a polypeptide at least 80% identical to SEQ ID NO:4 that have monooxygenase P450 activity. Furthermore, that person could use such sequences to make vectors and transgenic plants as described in the specification.

Thus the written description requirements have been met. Accordingly, the Applicants respectfully request these rejections be withdrawn.

VII. Enablement Rejections

Claims 1-8, 10-15 and 21-32 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. (Office Action mailed March 21, 2006, pages 7-11). In particular, the Examiner states, " . . . one of skill in the art would not know how to use the nucleic acids and vectors for prokaryotic or yeast expression (claims 11 and 14 are specifically not enabled for these reasons). The

Applicants respectfully disagree. In particular, the invention as claimed is enabled, for example, by describing a prokaryotic vector (pMLBART vector (Gleave, Plant Mol. Biol. 20, 1203-1207 (1992), see paragraph [0327] of the published application) and a yeast expression vector comprising a LUT1 cDNA, see, Figure 12 of the present application. Thus the Applicants believe that Claims 11 and 14 are enabled. The Tian paper cited by the Examiner merely indicates that initial attempts at expression in yeast were unsuccessful. There is no evidence that use of other methods known in the art and methods ad constructs described in the specification would be unsuccessful. Applicants further note that even though the Tian paper published after the filing data of the present application, it was clearly submitted before the present application was filed.

Further, the Examiner states: "it would require undue experimentation on the part of one skilled in the art to determine the results of expression SEQ ID NO:05 in a plant, and to elucidate what other steps (if any) would be required to generate a useful plant. . . . one of skill in the art would not know how to use the claimed expression vectors, nucleic acids, transgenic plants and seeds, and the methods recited in claims 28-32 are not enabled." (Office Action mailed March 21, 2006, page 10). The Applicants respectfully disagree. In particular, the invention as claimed is enabled, for example, by describing plants transgenically expressing SEQ ID NO:05. (*See*, Application as published, paragraph [0155]). Again, as s held by the Federal Circuit in Falkner, "Since the law is applied to each invention in view of the state of relevant knowledge, its application will vary with differences in the state of knowledge in the field and differences in the predictability of the science." Falkner, 448 F.3d at 1367-68. The Examiner has provided no evidence that the current invention is unpredictable as of the filing date of the invention. Instead, the Examiner has relied on outdated papers published in 1993 and 1998. Applicants respectfully submit that the claimed inventions were enabled as of the filing date of the present application.

Furthermore, expression of SEQ ID NO:05 in a plant produced a specific phenotype that was detected using assay for zeinoxanthin, specifically revealing one or two yellow bands of zeinoxanthin. (*See*, Application as published, paragraph [0325]). Thus SEQ ID NO:05 is capable of producing a desired carotenoid biosynthesis function.

Accordingly, the Applicants respectfully request these rejections for Claims 1-8, 10-15 and 21-32 be withdrawn.

VIII. Claims 1-8, 11-17, 21-22, and 24-28 are Rejected Under 35 U.S.C. §102 (e)

Claims 1-8, 11-17, 21-22, and 24-28 are rejected Under 35 U.S.C. §102 (e) as anticipated by United States Patent Application *20040216190* October 28, 2004 to Kovalic, filed December 18, 2003; hereinafter "the Kovalic *et al* reference." (Office Action mailed March 21, 2006, pages 11-13).

The Examiner admits the Kovalic *et al* reference teaches a sequence which is only 32.5% identical to SEQ ID NO:05. Applicants respectfully traverse this rejection since the sequence of the present invention is 80% identical to SEQ ID NO:04, see, amended claims. Accordingly, Applicants respectfully request withdrawal of this rejection.

IX. Claims 16 and 17 are Rejected Under 35 U.S.C. §102(b)

Claims 16 and 17 are rejected under 35 U.S.C. §102(b) as being anticipated by Comai *et al.*, (U.S. Patent No. 5187267, issued on Feb., 1993); hereinafter "the Comai *et al* reference." (Office Action mailed March 21, 2006, page 13). In particular, the Examiner states, "Comai *et al* teaches a eukarytic promoter that is active in a plant that was derived from the tomato heat shock protein, hsp80, (see, claim 1)." and further links "Because these claims [16 and 17] lack antecedent basis, (see 112 2nd rejections above), the limitations from the parent claim are not included." (Office Action mailed March 21, 2006, page 13). The Applicants point out that the amended Claims 16 and 17 include limitations from the parent claim. Applicants respectfully request these rejections be withdrawn.

X. Claims 1-8 and 10-12 are Rejected Under 35 U.S.C. §102(b)

Claims 1-8 and 10-12 are allegedly rejected under 35 U.S.C. §102(b) as being anticipated by Nyakatura *et al.* (GenBank Accession Number AL132958, 1999; hereinafter "the Nyakatura *et al* reference." (Office Action mailed March 21, 2006, page 13). In particular, the Examiner states, "Nyakatura *et al.* teaches a BAC clone that contains the genomic sequence comprising SEQ ID NO:05 of the instant application an

isolated nucleic acid sequence that exhibits 100% sequence identity with Applicants' SEQ ID NO:01 (sequence search results enclosed.). This BAC clone could be used as an expression vector wherein expression of the protein encoded by SEQ ID NO:5 is regulated by its own native promoter." (Office Action mailed March 21, 2006, page 13-14).

The present claims have been amended to include the limitation that the nucleic acid sequence is operably linked to a heterologous promoter. Applicants respectfully request these rejections be withdrawn.

XI. Claims 1, 5, 7, 11-13, 21-22, 24-26 and 28 are Rejected Under 35 U.S.C. §102(b)

Claims 1, 5, 7, 11-13, 21-22, 24-26 and 28 are rejected under 35 U.S.C. §102(b) as being anticipated by Siminszky et al., (U.S. Patent No. 6121512, issued on Sept. 19, 2000); hereinafter "the Siminszky *et al* reference." (Office Action mailed March 21, 2006, page 14-15). In particular, the Examiner states, "Siminszky *et al* teach a nucleic acid sequence encoding a P450 with 50.89% identity to SEQ ID NO:01 in the instant application. " The Applicants point out that Claims 1, 5, 7, 11-13, 21-22, 24-26 and 28, as amended, are not anticipated by the Siminszky *et al* reference as they require nucleic acid sequences encoded by polypeptide sequences at least 80% identical to SEQ ID NO:4. Applicants respectfully request these rejections be withdrawn.

XII. Claims 1, 11-12, 21-22, 24-26 and 28 are allegedly Rejected Under 35 U.S.C. §102(b)

Claims 1, 5, 7, 11-13, 21-22, 24-26 and 28 are allegedly rejected under 35 U.S.C. §102(b) as being anticipated by Bloksberg et al., (U.S. Patent No. 6410718 B1, issued on June 25, 2002); hereinafter "the Bloksberg *et al* reference." (Office Action mailed March 21, 2006, page 15).

In particular, the Examiner states, "Bloksberg *et al* teaches a nucleic acid encoding a polypeptide with 49.87% identity to SEQ ID NO:1 in the instant application."

The Applicants point out that Claims 1, 5, 7, 11-13, 21-22, 24-26 and 28, as amended, are not anticipated by the Bloksber *et al* reference as they require nucleic acid

sequences encoded by polypeptide sequences at least 80% identical to SEQ ID NO:4.. Applicants respectfully request these rejections be withdrawn.

XIII. Claims 1-8, 10-13, 15-17, 21-22, and 24-32 are allegedly Rejected Under 35 U.S.C. §103(a)

Claims 1-8, 10-13, 15-17, 21-22, and 24-32 are allegedly rejected under 35 U.S.C. §103(a) as being unpatentable by Siminszky *et al.* (U.S. Patent No. 6121512, issued on Sept. 19, 2000) as applied to claims 1, 5, 7, 11-13, 21-22, 24-26, and 28 above, in view of Nyakatura *et al.* (GenBank Accession AL132958, published on Dec. 21, 1999) and further in view of Ohkawa *et al.* (Pesticide Science (1999), 55:867-874). The Applicants point out that Claims 1-8, 10-13, 15-17, 21-22, and 24-32, as amended, are not unpatentable by Siminszky *et al.* in view of Nyakatura *et al.* and further in view of Ohkawa *et al.*

First, a *prima facie* case of obviousness must fail if the cited references do not disclose all the elements of the claims. Importantly, neither Siminszky *et al.* nor Nyakatura *et al.* nor Ohkawa *et al.* discloses the recited "nucleic acid sequence encoding a polypeptide at least 80% identical to SEQ ID NO:04." Importantly also, none of the references discloses the recited compositions and methods providing for expression vectors or transgenic plants. Because the references fail to disclose at least two elements of the claims, this, alone, negates a *prima facie* case of obviousness.

Second, a *prima facie* case of obviousness requires the cited references to provide one of ordinary skill in the art with motivation to modify the reference to arrive at the claimed invention. However, since neither Siminszky *et al.* nor Nyakatura *et al.* nor Ohkawa *et al.* discloses the recited compositions and methods providing for expression vectors or transgenic plants, there can therefore be no reasonable argument to provide motivation to combine such an element with others recited in the claims. This deficiency, standing alone, negates a *prima facie* case of obviousness.

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[2] MPEP 2143.03, citing *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

[3] *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598-99 (Fed. Cir. 1988) and *In re Jones*, 21 USPQ2d 1941, 1943 (Fed. Cir. 1992).

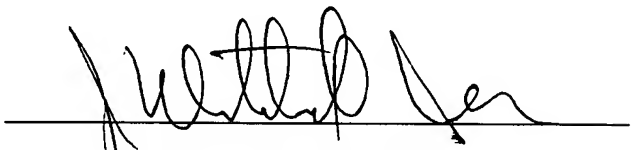
Third, a fundamental requisite of establishing a *prima facie* case of obviousness is that the prior art teaches a reasonable expectation of success in practicing the claimed invention. However, nothing in either Siminszky *et al.* or Ohkawa *et al.* suggests that combining the recited SEQ ID NO:05 in Nyakatura *et al.* with compositions and methods for providing expression vectors and transgenic plants would successfully produce transgenic plants expressing SEQ ID NO:05. Importantly, the specification of the present invention teaches compositions and methods for providing expression vectors and transgenic plants.

In view of Siminszky *et al.* and Nyakatura *et al.* and Ohkawa's silence on how to reasonably predict successful expression vectors and transgenic plants, this third prong of a *prima facie* case of obviousness remains lacking. This necessitates withdrawal of the rejection based on obviousness.

CONCLUSION

The Applicant believes the arguments set forth above traverse the Examiner's objections and rejections and therefore request these alleged grounds for objection and rejection be withdrawn. Should the Examiner believe a telephone interview would aid in the prosecution of this application, the Applicant encourages the Examiner to call the undersigned collect.

Dated: September 21, 2006



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[4] *In re Dow Chemical Co.*, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988) as cited in *In re Vaeck*, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991).